EXHIBIT 80

Department of Health and Human Services

OFFICE OF INSPECTOR GENERAL

COMPARISON OF REIMBURSEMENT PRICES FOR MULTIPLE-SOURCE PRESCRIPTION DRUGS IN THE UNITED STATES AND CANADA

Richard P. Kusserow
INSPECTOR GENERAL

OEI-03-91-00470

EXECUTIVE SUMMARY

PURPOSE

This report compares government reimbursement prices for multiple-source prescription drugs[1] in the United States and Ontario, Canada, and describes the potential for reducing Medicaid costs for such drugs. A companion report is entitled, "Strategies to Reduce Medicaid Drug Expenditures" (OEI-12-90-00800).

BACKGROUND

Most State Medicaid programs reimburse for prescription drugs. Prices are determined in accordance with regulations issued by the Health Care Financing Administration (HCFA). These regulations establish maximum allowable prices for multiple-source prescription drugs, designated by HCFA as "upper limit" drugs.

In the last decade, Medicaid prescription drug expenditures have risen at a faster rate than the number of recipients. Between Fiscal Years 1982 and 1989, expenditures climbed from $1.6 billion to $3.7 billion, an increase of 131 percent. The number of Medicaid recipients grew by only 16 percent, from 13.7 to 15.9 million. While the Omnibus Reconciliation Act of 1990 established a rebate program to reduce drug expenditures, it does not affect HCFA's formula for determining upper limit reimbursement prices.

METHODOLOGY

We made two comparisons of January 1989 reimbursement prices (exclusive of dispensing fees) for multiple-source prescription drugs. Both compared products that matched in dosage form and strength. We first compared prices on HCFA's upper limit drug list (139 drugs) to prices in Ontario's *Drug Benefit Formulary and Comparative Drug Index.* Then we compared prices of the most commonly used drugs (a subset of products from the first comparison).

FINDINGS

More drug prices were lower on the HCFA upper limit list than in Ontario.

[1]In this report, the term "drug" refers to a generic compound, e.g., Amoxicillin, while the term "product" refers to a dosage form and strength of the drug, e.g., Amoxicillin Capsule 500 mg.

- Of the 87 matching drugs, 40 had lower prices on HCFA's list and 33 had lower prices in Ontario. The remaining 14 were the same price or had some products with higher Ontario prices and some with higher HCFA prices.

- In contrast, the companion OIG report found that almost all (46 of 49) brand-name prescription drugs had lower prices in Canada. (While HCFA sets national upper limit prices for multiple source drugs, it only recommends a pricing methodology for brand name drugs. The States set actual prices.)

Over half of the commonly used drugs had lower prices in Ontario.

- Of the 20 matching drugs, 11 had lower Ontario prices and 3 had lower HCFA prices. Product prices for the remaining six drugs were mixed.

Medicaid could save $2.2 million in five sample States if lower Ontario prices were paid.

RECOMMENDATION

The HCFA should review products with lower Ontario reimbursement prices to ensure that they are properly priced on the upper limit list.

COMMENTS

We received comments from HCFA, the Assistant Secretary for Planning and Evaluation (ASPE), and the Assistant Secretary for Management and Budget (ASMB).

The HCFA disagreed with our recommendation. They believe that comparing U.S. and Canadian drug pricing is not useful because of "enormous differences" between the two systems. We believe the comparison is valid. It provides HCFA with information on what another system pays for multiple source drugs.

The ASPE and ASMB noted the Omnibus Budget Reconciliation Act of 1990 prohibits changing the formula used to determine reimbursement rates. However, our recommendation is not for HCFA to change the reimbursement formula but to ensure that upper limit prices were calculated correctly for drugs that were less expensive in Ontario.

The full text of comments appears in Appendix C.

TABLE OF CONTENTS

INTRODUCTION

PURPOSE

This report compares government reimbursement prices for multiple-source prescription drugs[1] in the United States and Ontario, Canada, and describes the potential for reducing Medicaid costs for such drugs. A companion report is entitled, "Strategies to Reduce Medicaid Drug Expenditures," (OEI-12-90-00800).

BACKGROUND

Reimbursement for prescription drugs is an optional Medicaid service which most States provide.

In the last decade, Medicaid expenditures for prescription drugs have risen at a faster rate than the number of recipients. Between Fiscal Years 1982 and 1989, expenditures climbed from $1.6 billion to $3.7 billion, an increase of 131 percent. The number of Medicaid recipients grew by only 16 percent, from 13.7 to 15.9 million.

In 1983, a Department of Health and Human Services task force advised that savings could be accrued through the use of multiple source drugs. A multiple source drug is one for which one or more equivalent products are marketed. Multiple source drugs are generally less expensive than single-source brand name drugs.

The HCFA's Upper Limit Drugs and Reimbursement Prices

The Health Care Financing Administration (HCFA) is responsible for Federal administration of the Medicaid program. It establishes maximum allowable reimbursement prices for prescription drugs and products which it defines as "upper limit" drugs. The HCFA and the Office of Inspector General (OIG) perform reviews to ensure compliance with upper limit regulations.

While the Omnibus Budget Reconciliation Act of 1990 established a drug rebate program to reduce drug expenditures, the program will not affect the formula used to determine reimbursement prices for upper limit drugs.

---

[1]In this report, the term "drug" refers to a generic compound, e.g., Amoxicillin, while the term "product" refers to a dosage form and strength of the drug, e.g., Amoxicillin Capsule 500 mg.

At the time of our inspection, HCFA designated multiple source drugs as upper limit drugs when two conditions are met: (1) all formulations of the drug approved by the Food and Drug Administration (FDA) have been evaluated as therapeutically equivalent in the most current edition of their publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (including supplements or in successor publications), and (2) at least three suppliers list the drug in current editions of published national drug compendia (42 CFR 447.332).[2]

Ontario's Reimbursement Price

In the Canadian province of Ontario, payments for prescription drugs are based on the best available price (BAP). According to Ontario's *Drug Benefit Formulary/Comparative Drug Index*, the BAP is the lowest amount (calculated per appropriate unit) for which a listed product of a drug can be purchased in Canada for sale in Ontario. The value of any price reduction granted by the manufacturer, wholesaler, or their representatives in the form of rebates, discounts, refunds, free goods, or any other like benefits is then deducted from the BAP. Finally, a percentage--usually 10 percent--is added to arrive at the reimbursement price.

METHODOLOGY

We made two comparisons of 1989 reimbursement prices (exclusive of dispensing fees) for multiple-source prescription drugs. Both were comparisons of products that matched in dosage form and strength.

In the first instance, we compared prices on HCFA's upper limit drug list (139 drugs) to prices in Ontario's *Drug Benefit Formulary and Comparative Drug Index*. In the second, we compared prices of the most commonly used drugs (a subset of products from the first comparison).

When we found products that matched, we converted the Ontario prices to U.S. prices (using the exchange rate effective on March 1, 1989) and calculated the difference.

To determine potential Medicaid savings:

1) We selected five States which together accounted for 38 percent of Medicaid's prescription drug expenditures in 1988. The States were: California, Michigan, New York, Ohio, and Pennsylvania.

---

[2]For more information, see FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations.*

2) We determined each State's utilization (i.e., number of units used in each State) of the matching HCFA upper limit and Ontario products.

3) We proceeded with the assumption that the States use upper limit reimbursement prices.[3] For products with a lower Ontario price, we calculated the difference between Ontario's and HCFA's price per unit and multiplied it by the number of units used in each State.

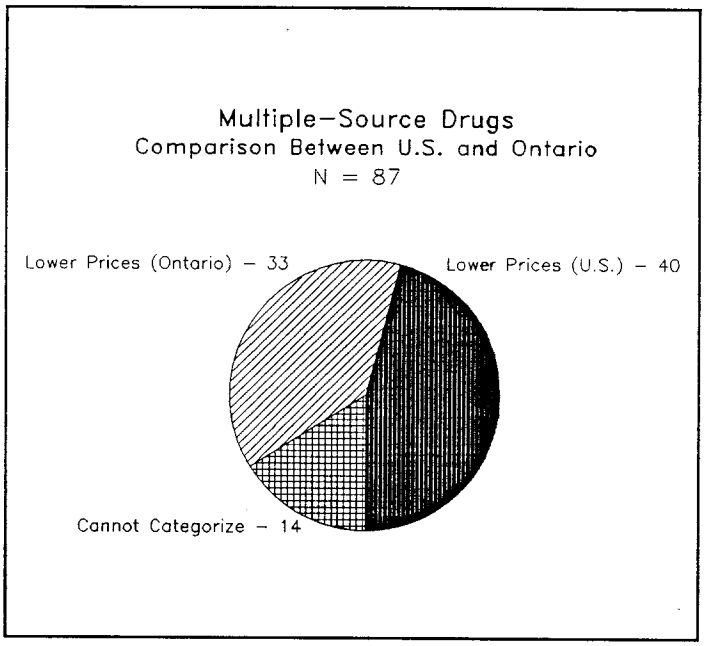
[3]A State's total payment for upper limit drugs may not exceed the aggregate of the drugs' unit prices as established by HCFA.

FINDINGS

MORE DRUG PRICES WERE LOWER ON THE HCFA UPPER LIMIT LIST THAN IN ONTARIO.

Eighty-seven multiple source drugs appeared on both HCFA's upper limit drug list and Ontario's drug benefit index.

As shown in the chart below, 33 drugs had lower prices in Ontario, while 40 had lower prices on the HCFA list. The 14 remaining drugs did not fall into either category: 1 drug had no price difference, and 13 drugs had some products with higher Ontario prices and some with higher HCFA prices.



The 87 matching drugs represented a total of 178 matching products. For 85 products, Ontario prices were lower by 0.1 to 90.8 percent. Thirty-eight of the 85 product prices were over 50 percent lower. The greatest price difference was for Trifluoperazine Hydrochloride (Stelazine).[4] (See appendices for listings of products with lower Ontario reimbursement prices.)

[4]Brand names appear in parentheses.

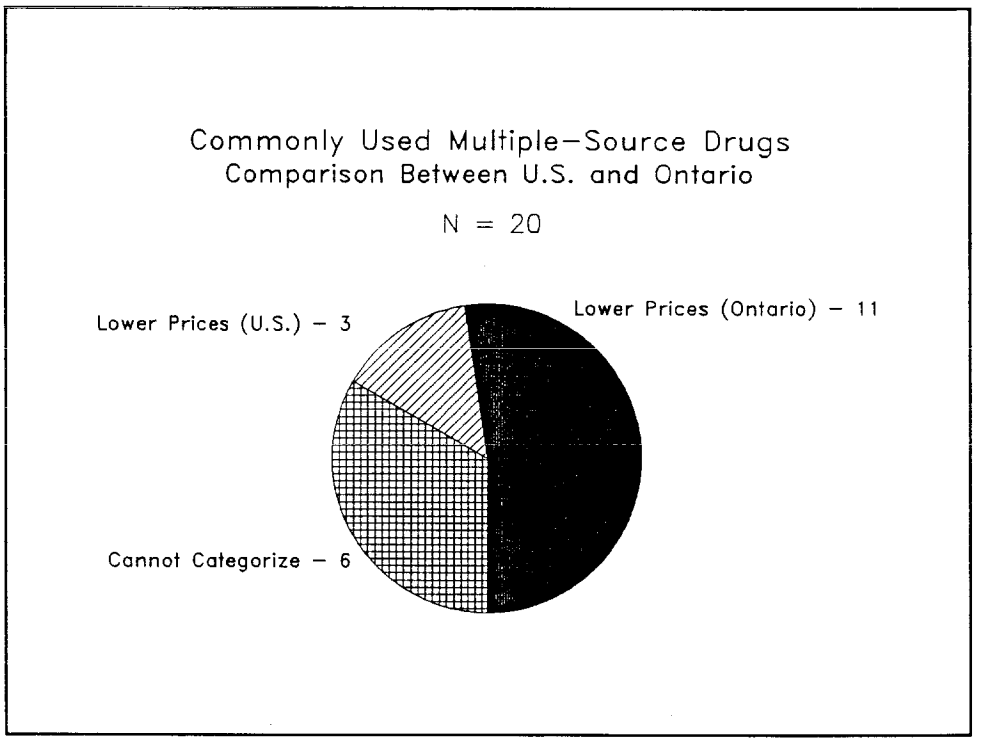
The HCFA, on the other hand, had lower prices for 92 products. The range of price difference was from 4.1 to 1186.8 percent. Thirteen of the 92 products were lower by more than 500 percent.

Of the 178 matching products, one had no price difference.

The above findings reveal that fewer than half (33 out of 87) of the multiple-source prescription drugs were less expensive in Ontario. By way of contrast, the companion OIG report found that almost all (46 out of 49) brand-name prescription drugs had lower reimbursement prices in Canada. (While HCFA sets national upper limit prices for multiple-source prescription drugs, it only recommends a pricing methodology for brand-name prescription drugs. The reimbursement prices for brand-name prescription drugs are set by individual States.)

OVER HALF OF THE COMMONLY USED DRUGS HAD LOWER PRICES IN ONTARIO.

Twenty of the most commonly used U.S. multiple source drugs appeared on both the HCFA upper limit drug list and in the Ontario drug benefit index. Eleven had lower prices in Ontario and three had lower prices on the HCFA list. Six did not fit into either category: each of the six had some products with higher Ontario prices and some products with higher HCFA prices. This is illustrated in the chart below.[9]



Diazepam (Valium) was the least expensive of the commonly used drugs. Depending on dosage form and strength, the price difference was from 79.9 to 86.2 percent lower in Ontario. (See Appendix B for a complete list of commonly used products with lower Ontario reimbursement prices.)

MEDICAID COULD SAVE $2.2 MILLION IN FIVE SAMPLE STATES IF LOWER ONTARIO PRICES WERE PAID.

Savings could amount to $1.3 million in five sample States if lower Ontario prices, for commonly used drugs, were paid. Of the $1.3 million, approximately $0.9 million (68 percent) could be saved on three drugs alone: Cephalexin (Keflex), Acetaminophen with Codeine (Tylenol with Codeine), and Furosemide (Lasix). Thirteen other drugs account for the remaining $0.4 million.

An additional $0.9 million could be saved in the five sample States on drugs which are not regarded as most common. About 61 percent of the $0.9 million represents the following three drugs: Carbamazepine (Tegretol), Flurazepam Hydrochloride (Dalmane), and Methyldopa (Aldomet). Nine other drugs make up the remaining $0.3 million.

RECOMMENDATION

The HCFA should review products with lower Ontario reimbursement prices to ensure that they are properly priced on the upper limit list.

APPENDIX A

APPENDIX A

UPPER LIMIT PRODUCTS WITH LOWER ONTARIO PRICES *

GENERIC NAME	HCFA PRICE	ONTARIO PRICE	ONTARIO PRICE +10%	CONVERTED ONTARIO PRICE	DOLLAR DIFFERENCE	PERCENT DIFFERENCE
TRIFLUOPERAZINE HYDROCHLORIDE Tab 2 mg	0.0598	0.0060	0.0066	0.0055	0.0543	90.8%
TRIFLUOPERAZINE HYDROCHLORIDE Tab 5 mg	0.0742	0.0086	0.0095	0.0079	0.0663	89.4%
TRIFLUOPERAZINE HYDROCHLORIDE Tab 10 mg	0.0892	0.0142	0.0156	0.0130	0.0762	85.4%
BETAMETHASONE VALERATE Cream 0.1% 15 gm	0.1353	0.0225	0.0248	0.0206	0.1147	84.8%
BETAMETHASONE VALERATE Ointment 0.1% 15 gm	0.1353	0.0244	0.0268	0.0223	0.1130	83.5%
PHENYLBUTAZONE Tab 100 mg	0.0607	0.0110	0.0121	0.0101	0.0506	83.4%
HYDROCHLOROTHAZIDE & TRIAMTERENE Tab 25 mg & 50 mg	0.2316	0.0484	0.0532	0.0443	0.1873	80.9%
CLOFIBRATE Cap 500 mg	0.1870	0.0431	0.0474	0.0395	0.1475	78.9%
BETAMETHASONE VALERATE Cream 0.1% 45 gm	0.0884	0.0225	0.0248	0.0206	0.0678	76.7%
FLURAZEPAM HYDROCHLORIDE Cap 15 mg	0.1342	0.0346	0.0381	0.0317	0.1025	76.4%
OXTRIPHYLLINE Tab 200 mg	0.0882	0.0230	0.0253	0.0211	0.0671	76.1%
FLURAZEPAM HYDROCHLORIDE Cap 30 mg	0.1492	0.0394	0.0433	0.0361	0.1131	75.8%
BETAMETHASONE VALERATE Ointment 0.1% 45 gm	0.0884	0.0244	0.0268	0.0223	0.0661	74.7%
CLOXACILLIN SODIUM Cap 250 mg	0.3051	0.0933	0.1026	0.0854	0.2197	72.0%
METHYLDOPA Tab 125 mg	0.1102	0.0343	0.0377	0.0314	0.0788	71.5%
HYDROCHLOROTHIAZIDE & METHYLDOPA Tab 15 mg & 250 mg	0.1852	0.0681	0.0749	0.0624	0.1228	66.3%
THIORIDAZINE HYDROCHLORIDE Tab 10 mg	0.0369	0.0137	0.0151	0.0125	0.0244	66.0%
CLORAZEPATE DIPOTASSIUM Cap 3.75 mg	0.1643	0.0621	0.0683	0.0569	0.1074	65.4%
ACETAZOLAMIDE Tab 250 mg	0.0600	0.0251	0.0276	0.0230	0.0370	61.7%
HYDROCHLOROTHIAZIDE & METHYLDOPA Tab 25 mg & 250 mg	0.1942	0.0704	0.0774	0.0645	0.1297	66.8%
CLOXACILLIN SODIUM Cap 500 mg	0.4260	0.1829	0.2012	0.1675	0.2585	60.7%
PROPANTHELINE BROMIDE Tab 15 mg	0.0852	0.0368	0.0405	0.0337	0.0515	60.5%
THIORIDAZINE HYDROCHLORIDE Tab 25 mg	0.0583	0.0257	0.0283	0.0235	0.0348	59.6%
CARBAMAZEPINE Tab 200 mg	0.1493	0.0876	0.0964	0.0802	0.0691	46.3%
HALOPERIDOL Tab 0.5 mg	0.0765	0.0451	0.0496	0.0413	0.0352	46.0%
THIORIDAZINE HYDROCHLORIDE Tab 50 mg	0.0787	0.0465	0.0512	0.0426	0.0361	45.9%
CLORAZEPATE DIPOTASSIUM Cap 7.5 mg	0.2242	0.1369	0.1506	0.1254	0.0988	44.1%
CHLORDIAZEPOXIDE HYDROCHLORIDE Cap 5 mg	0.0177	0.0108	0.0119	0.0099	0.0078	44.1%
TRIHEXPHENIDYL HYDROCHLORIDE Tab 2 mg	0.0135	0.0088	0.0097	0.0081	0.0054	40.3%
TOLBUTAMIDE Tab 500 mg	0.0340	0.0222	0.0244	0.0203	0.0137	40.2%
CHLORDIAZEPOXIDE HYDROCLORIDE Cap 25 mg	0.0252	0.0169	0.0186	0.0155	0.0097	38.6%
CHLORDIAZEPOXIDE HYDROCHLORIDE Cap 10 mg	0.0188	0.0129	0.0142	0.0118	0.0070	37.2%
TRIHEXPHENIDYL HYDROCHLORIDE Tab 5 mg	0.0165	0.0114	0.0125	0.0104	0.0061	36.7%
METHYLDOPA Tab 250 mg	0.0825	0.0580	0.0638	0.0531	0.0294	35.6%
PHENYTOIN SODIUM Cap 100 mg	0.0675	0.0476	0.0524	0.0436	0.0239	35.4%
MEPERIDINE HYDROCHLORIDE Tab 50 mg	0.1275	0.0920	0.1012	0.0842	0.0433	33.9%
CHLORTHALIDONE Tab 25 mg	0.0318	0.0230	0.0253	0.0211	0.0107	33.8%
METHYLDOPA Tab 500 mg	0.1500	0.1107	0.1218	0.1014	0.0486	32.4%

THIOTHIXENE HYDROCHLORIDE Cap 2 mg	0.2137	0.1608	0.1769	0.1472
THIORIDAZINE HYDROCHLORIDE Cap 100 mg	0.1204	0.0932	0.1025	0.0853
HALOPERIDOL Tab 1 mg	0.0919	0.0731	0.0804	0.0669
FLUOCINONIDE Cream Top .05% 15 gm	0.3200	0.2791	0.3070	0.2556
PRIMIDONE Tab 250 mg	0.0570	0.0500	0.0550	0.0458
SULFACETAMIDE SODIUM Solution/Drops; Ophth	0.0880	0.0784	0.0862	0.0718
HALOPERIDOL Tab 2 mg	0.1455	0.1318	0.1450	0.1207
HALOPERIDOL Tab 5 mg	0.2083	0.1894	0.2083	0.1734
SULFISOXAZOLE Tab 500 mg	0.0375	0.0348	0.0383	0.0319
THIOTHIXENE HYDROCHLORIDE Cap 10 mg	0.3771	0.3560	0.3916	0.3260
CLORAZEPATE DIPOTASSIUM Cap 15 mg	0.2242	0.2338	0.2572	0.2141
PROPRANOLOL HYDROCHLORIDE Tab 10 mg	0.0183	0.0193	0.0212	0.0177
QUINIDINE SULFATE Tab 200 mg	0.0562	0.0595	0.0655	0.0545

* This list does not include commonly used upper limit products.
  Prices are per unit of the product, e.g., per tablet, per milligram.

APPENDIX B

APPENDIX B

COMMONLY USED UPPER LIMIT PRODUCTS WITH LOWER ONTARIO PRICES *

GENERIC NAME	HCFA PRICE	ONTARIO PRICE	ONTARIO PRICE +10%	CONVERTED ONTARIO PRICE	DOLLAR DIFFERENCE	PERCENT DIFFERENC
DIAZEPAM Tab 10 mg	0.038500	0.005800	0.006380	0.005311	0.033189	86.2
DIAZEPAM Tab 5 mg	0.028000	0.005000	0.005500	0.004578	0.023422	83.6
DIAZEPAM Tab 2 mg	0.021000	0.004600	0.005060	0.004212	0.016788	79.9
FUROSEMIDE Tab 20 mg	0.020700	0.005400	0.005940	0.004944	0.015756	76.1
ALLOPURINOL Tab 300 mg	0.138700	0.041000	0.045100	0.037541	0.101159	72.9
ALLOPURINOL Tab 100 mg	0.056300	0.016800	0.018480	0.015383	0.040917	72.7
HYDROCORTISONE Cream Top 1%, 20mg	0.060000	0.018900	0.020790	0.017306	0.042694	71.2
FUROSEMIDE Tab 40 mg	0.022200	0.008100	0.008910	0.007417	0.014783	66.6
IMIPRAMINE HCL Tab 25 mg	0.023700	0.009000	0.009900	0.008241	0.015459	65.2
HYDROCORTISONE Cream Top 1% 30mg	0.048000	0.018900	0.020790	0.017306	0.030694	63.9
IMIPRAMINE HCL Tab 50 mg	0.034200	0.015500	0.017050	0.014192	0.020008	58.5
METRONIDAZOLE Tab 250 mg	0.058600	0.028000	0.030800	0.025638	0.032962	56.2
ERYTHROMYCIN Tab 250 mg	0.104500	0.051000	0.056100	0.046698	0.057802	55.3
CEPHALEXIN Cap 500 mg	0.674900	0.335400	0.368940	0.307106	0.367794	54.5
CEPHALEXIN Cap 250 mg	0.341100	0.170400	0.187440	0.156025	0.185075	54.3
HYDROCHLOROTHIAZIDE Tab 25 mg	0.009000	0.005000	0.005500	0.004578	0.004422	49.1
HYDROCHLOROTHIAZIDE Tab 50 mg	0.009700	0.006000	0.006600	0.005494	0.004206	43.4
TETRACYCLINE Cap 250 mg	0.029200	0.019500	0.021450	0.017855	0.011345	38.9
LORAZEPAM Tab 1 mg	0.071200	0.049700	0.054670	0.045507	0.025693	36.1
ACETAMINOPHEN w/CODEINE Tab 15 mg	0.043800	0.031700	0.034870	0.029026	0.014774	33.7
ACETAMINOPHEN w/CODEINE Tab 30 mg	0.046500	0.034100	0.037510	0.031223	0.015277	32.9
LORAZEPAM Tab 0.5 mg	0.057700	0.043900	0.048290	0.040197	0.017503	30.3
NYSTATIN Tab Vaginal 100,000 units 15's	0.176000	0.135900	0.149490	0.124435	0.051565	29.3
LORAZEPAM Tab 2 mg	0.104200	0.080900	0.088990	0.074075	0.030125	28.9
NYSTATIN Ointment Top 100,000 un/gm 15	0.100000	0.090400	0.099440	0.082774	0.017226	17.2
ERYTHROMYCIN STERATE Tab 250 mg	0.089200	0.081600	0.089760	0.074716	0.014484	16.2
NYSTATIN Tab Vaginal 100,000 units 30's	0.148000	0.135900	0.149490	0.124435	0.023565	15.9
AMOXICILLIN Cap 500 mg	0.198000	0.189000	0.207900	0.173056	0.024944	12.6
IBUPROFEN Tab 600 mg	0.082300	0.080000	0.088000	0.073251	0.009049	11.0
AMOXICILLIN Cap 250 mg	0.099000	0.097000	0.106700	0.088817	0.010183	10.3
NYSTATIN Ointment Top 100,000 un/gm 30	0.087700	0.090400	0.099440	0.082774	0.004926	5.6
NYSTATIN Cream Top 100,000 un/gm 15	0.075300	0.079600	0.087560	0.072885	0.002415	3.2
NYSTATIN Oral 100,000 un/5ml 60ml susp	0.052500	0.056700	0.062370	0.051917	0.000583	1.1
AMPICILLIN Cap 500 mg	0.136800	0.149300	0.164230	0.136705	0.000095	0.1

* Prices are per unit of the product, e.g., per tablet, per milligram.

APPENDIX C

COMMENTS AND OIG RESPONSE

Health Care Financing Administration (HCFA)

The HCFA did not agree with our recommendation to review products with lower Ontario reimbursement prices to ensure they are properly priced on the upper limit list. According to HCFA, comparing U.S. and Canadian prices would not provide useful information due to "enormous differences" in the two systems for purchase of prescription drugs.

While we are aware of the differences in the two systems, we believe that a valid comparison can be made for drug costs. With the differences in mind, the results of the comparison should provide HCFA with information on what another system pays for multiple source drugs. By calculating the cost savings for drugs that were less expensive in Ontario, we showed the impact lower Ontario prices could have on Medicaid reimbursement if upper limit prices were not correct. This information could also help HCFA target efforts on drugs that appear to be excessively priced.

The HCFA also suggested that we expand our review to include drug dispensing fees. We are aware that total reimbursement includes both the drug cost and the dispensing fee. As we stated in the methodology section, our comparison was for drug cost only. We did not review dispensing fees. This is consistent with HCFA upper limit regulations which provide upper limit prices for drug cost only.

The HCFA upper limit regulations allow States to establish their own dispensing fee, and they vary considerably from State to State. We agree that a study including both the drug cost and dispensing fee could be very valuable.

Assistant Secretary for Management and Budget (ASMB) and Assistant Secretary for Planning and Evaluation (ASPE)

The ASMB and ASPE were concerned about the implementation of our recommendation in light of the Omnibus Reconciliation Act (OBRA) of 1990. The OBRA prohibits change to the formula used for determining reimbursement rates. Our recommendation, however, does not advocate that HCFA change the formula. It calls for HCFA to ensure that upper limit prices were calculated correctly.

(The full text of comments from HCFA, ASMB, and ASPE are included in this appendix.)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care Financing Administration

Memorandum

Date MAY 13 1991

From Gail R. Wilensky, Ph.D.
Administrator

Subject OIG Draft Report - "Comparison of Reimbursement Prices for Multiple Source Prescription Drugs in Canada and the United States (U.S.)," (OEI-03-91-00470)

To The Inspector General
Office of the Secretary

We have reviewed the subject draft report which presents OIG's findings of a study which: (1) compared government prices paid for multiple-source prescription drugs in Ontario, Canada and the U.S.; and (2) determined the potential for reducing Medicaid costs for such drugs.

This draft report concludes that based on the utilization of drugs in five sampled States, the total annual expenditure for those States could be reduced by $2.2 million, if the Medicaid upper limit prices were replaced by lower Ontario prices. As a result of this finding, OIG recommends that HCFA review products with lower Ontario payment prices to ensure that they are properly priced on the upper limit list. While we agree that the Medicaid program should pay less for multiple-source prescription drugs, we do not agree with OIG's recommendation. Our specific comments on the recommendation are attached.

Thank you for the opportunity to review and comment on this draft report. Please advise us whether you agree with our position on the report's recommendation at your earliest convenience.

Attachment

IG	✓
DIG	✓
DIG-AS	
DIG-EI	✓
DIG-OI	
AIG-MP	✓
OGC/IG	✓
EX SEC	
DATE SENT	5/13

Comments of the Health Care Financing Administration on the OIG Draft Report - Comparison of Reimbursement Prices for Multiple-Source Prescription Drugs in Canada and the United States OEI-03-91-00470

Recommendation

HCFA should review products with lower Ontario reimbursement prices to ensure that they are properly priced on the upper limit list.

HCFA Response

Although we agree that Medicaid should pay less for multiple source prescription drugs, we do not believe that comparing Canadian drug product pricing to U.S. drug product pricing would yield the useful information we need to affect Medicaid drug expenditures. As we have stated in our response to the OIG draft report on "Strategies to Reduce Medicaid Drug Expenditures," the enormous differences between U.S. and Canadian systems for the purchase of prescription drugs for our respective Government health programs preclude the use of Canadian comparisons as a basis for U.S. drug savings estimates.

Canada has a national health insurance program which allows the Canadian government to buy drugs directly from the manufacturer and to negotiate prices for those drugs. Further, the Canadian government has the authority to determine whether or not a drug will be marketed in Canada and at what price. This is not the case in the U.S. Employing negotiating tools similar to those used by the Canadians would require legislation that might face strong opposition in this country.

General Comments

- While OIG's findings appear to provide a valid representation of the differences in the cost of the drug component of prescription expenditures between Canada and the United States, the report provides only a partial answer to the question of whether a decrease in U.S. expenditures could be anticipated by adoption of the same pricing policies as those employed in Canada. In order to answer this question, OIG should include information in the report concerning total reimbursement in Ontario and the U.S. This report only discusses drug costs and does not address the impact of dispensing fees on total reimbursement. Assuming that a given level of total reimbursement is required to provide adequate remuneration to participating pharmacies, decreases in ingredient cost reimbursement can be balanced by increases in the dispensing fee. It is possible that the Canadian system is comparatively stricter in controlling the former

and more lax in controlling the latter. If this is true, then the assumption that one can transplant only the pattern of ingredient cost reimbursement to the Medicaid program is inappropriate, since this decision is based upon information on only one of the two components of total reimbursement. We suggest that additional information on total reimbursement be included in the final inspection report.

- An unknown amount of the Canadian savings was obtained because "Canada is benefiting from research and development (R&D) of drugs in the U.S. but is not compensating manufacturers for these costs within the price structure established in Canada." We believe that R&D costs ought to be fairly compensated as a part of reimbursement, therefore, "compensating manufacturers for these costs" would limit the savings that could be achieved.

- As a minor point, it is noted that on Page i, Background section of the Executive Summary, the statement is made that "... Medicaid expenditures for prescription drugs have risen faster than the number of recipients using them." We believe that OIG's intention is to say that the percentage increase in expenditures for prescription drugs under the Medicaid program was in excess of the percentage increase in the number of recipients.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Washington, D.C. 20201

MAR 12 1991

Memorandum to: Richard Kusserow
Inspector General

From: Kevin Moley
Assistant Secretary for Management and Budget

Subject: OIG Draft Report: "Comparison of Reimbursement Prices for Multiple-Source Prescription Drugs in Canada and the United States" 03-91-00470

We would recommend that the OIG reconsider the proposal in this report in light of the actions taken by the Congress in OBRA 90. Section 4401 of that Act prohibits the Secretary from changing the formula used in determining reimbursement rates for outpatient prescription drugs until after December 31, 1994. Congress took this action in order to allow adequate time to evaluate the impact of the rebate provisions also enacted in OBRA 90. It is extremely doubtful, therefore, that Congress would be receptive to a recommendation for immediate repeal of this provision, especially considering the relatively small savings that could be expected.

On a more technical level, the report compares the highest possible HCFA prices to the lowest possible prices in Ontario. Is there evidence to indicate that these represent prices actually paid?

IG	✓
PDIG	✓
DIG-AS	✓
DIG-EI	✓
DIG-OI	
AIG-MP	✓
OGC/IG	
EX SEC	✓
DATE SENT	3/14

1991 MAR 14 PM 2:15

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Washington, D.C. 20201

MAR 12 1991

IG	✓
PDIG	✓
DIG-AS	
DIG-EI	✓
DIG-OI	
AIG-MP	✓
OGC/IG	
EX SEC	✓
DATE SENT	3/14

1991 MAR 14 PM 3:49

TO: Richard P. Kusserow
Inspector General

FROM: Assistant Secretary for
Planning and Evaluation

SUBJECT: OIG Draft Report: "Comparison of Reimbursement Prices for Multiple-Source Prescription Drugs in Canada and the United States"--COMMENTS 03-91-00470

Thank you for providing ASPE with a copy of this draft report for our review and comment.

The draft report provides a clear and highly readable summary. The lower Canadian prices for high volume multiple-source drugs found by the OIG suggests that Medicaid upper limit prices for these drugs may be too high. However, the draft report's recommendation to review these prices should be discussed in more detail in the final report. Because OBRA 90, Sec. 4401 (f)(1), prohibits HHS from modifying the formula used to determine reimbursement limits before December 31, 1994, the mechanism HCFA could use to act on this recommendation is unclear.

We appreciate the limitations inherent in short term studies and realize that studies do not have to be analytically perfect to be useful. However, the final report would be more persuasive if the following technical limitations were discussed and appropriate caveats about generalizing from the findings were provided:

- The limitation of data for one month. Administered price mechanisms such as Ontario's undoubtedly lag behind changes in U.S.-Canadian Dollar exchange rates. The lower Canadian prices relative to U.S. prices observed in this inspection may have been caused in part by exchange rate fluctuations rather than being the result of true long term lower prices.

- The limitation of regional patterns of practice. The savings suggested by the OIG inspection are for high volume U.S. drugs, not across the board for all 178 matching multiple source products. Since higher demand often produces higher prices, many products may be cheaper in Canada because these products are prescribed significantly less often by Ontario physicians. Wide prescribing differences are known to exist among regions in the U.S. and Canada.

- The limitation of extrapolating from sample data. The OIG report is based on data which are in fact samples of price data both in time and in the number of multiple-source drugs under the two systems. Some apparent differences could be explained by normal sampling variation. For example, the results on page 4 (N=87, Ontario prices greater = 40, U.S. prices greater = 33, no difference = 14) would not rule out the null hypothesis that the expected long run average price for both countries was the same with 95 percent confidence.

Nancy C. Gilmore for
Martin H. Gerry